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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,586	02/11/2004	Percy H. Carter	QA0286 NP	5361
23914 7590 12/27/2006 LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			EXAMINER KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/27/2006	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/776,586	Applicant(s) CARTER ET AL.	
	Examiner Joseph Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 11-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/3/04, 3/16/05, 7/11/05</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-26 are pending in the instant application.

#### ***Election/Restrictions***

Applicant's election of Group I (Claims 1-10) along with an election of species in the reply filed on October 25, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

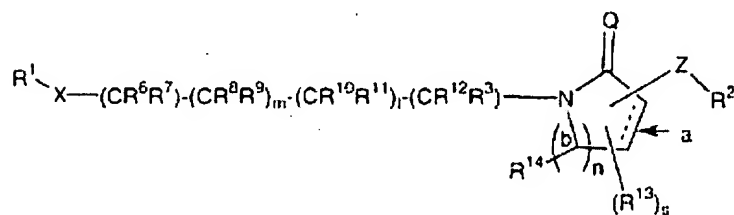
Applicant has stated in the response that Group I encompassed claims 1-19, however since the Restriction Requirement made on October 2, 2006 stated that Group I encompassed claims 1-10 and Applicant has not made a traversal that Group I should encompass claims 1-19, the election is limited to claims 1-10.

#### ***Status of the Claims***

Claims 1-26 are pending in the instant application. Claims 1-5 (in part), 6-8, 9-10 (in part), and 11-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Art Unit: 1626

Pursuant to Applicant's election of a species, the scope of the invention will be limited to the following substitutions of the base structure



where:

- n is 1;
- Z is -NR<sup>18</sup>C(O)-;
- X is as defined for claim 1;
- Q is O;
- All other substituents will be as defined.

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1-5 and 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl, piperidinyl, imidazolyl, pyrrolidinyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 244(+) (diazines), class 546 subclass 184(+) (piperidines), 546 subclass 249(+) (pyridines), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which

anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

***Priority***

The claim to priority of US Serial Number 60/446,976 filed February 12, 2003 is acknowledged in the instant application.

***Information Disclosure Statement***

The Information Disclosure Statements filed June 3, 2004, March 16, 2005, and July 11, 2005 have been considered fully by the Examiner.

***Claim Objections***

Claims 1-5 and 9-10 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

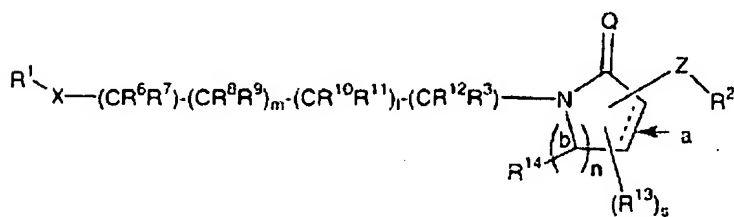
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Choi-Sledeski et al. (WO 99/62904 A1) in view of Patani et al. (*Chem Rev.* 1996, 3147-3176) and *In re Wood* (199 USPQ 137).

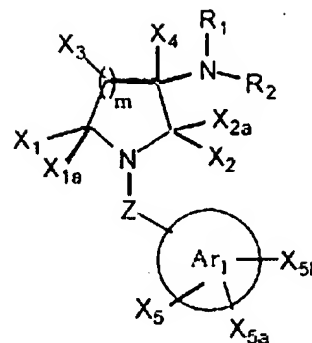
The instant invention is drawn to compounds and compositions of Formula I



where:  $n$  is 1;  $Z$  is  $-NR^{18}C(O)-$ ;

$X$  is as defined for claim 1;  $Q$  is  $O$ ; and all other substituents will be as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)



Choi-Sledeski et al. teach compounds of the formula:

where  $X_2$  and  $X_{2a}$  are taken together to form oxo, Z is  $-(CH_2)_2NR''(CH_2)-$ ,  $R_2$  is  $R_3S(O)_{1-2-}$ , and all other substituents are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP

§2141.02)

Choi-Sledeski et al. do not teach the proviso set forth in claim 1 that  $R^3$  is not H if  $R^6$  is H or the amide in the Z group of the instant compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137

Patani et al. teach the non-classical bioisosteric replacement of a sulfonyl for a carbonyl with comparable pharmaceutical activity and that they are art recognized replacements. See pages 3166-3167, especially Table 39 and Figure 67.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Choi-Sledeski et al., substitute methyl for hydrogen where needed, and replace the sulfonyl for a carbonyl to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Choi-Sledeski et al. Choi-Sledeski et al. teach the use of the synthesized compounds to be factor Xa inhibitors. See page 2, lines 8-10.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

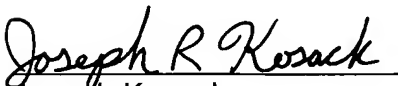
### **Conclusion**

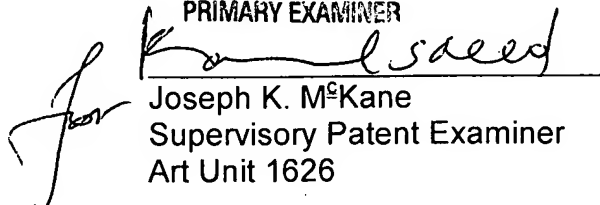
Claims 1-5 and 9-10 are rejected. Claims 1-5 and 9-10 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph Kosack  
Patent Examiner  
Art Unit 1626

KAMALA A. SAEED, PH.D.  
PRIMARY EXAMINER  
  
Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner  
Art Unit 1626